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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,997

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Peiyuan Wang

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12/17/2008

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

12/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,997	Applicant(s) WANG ET AL.	
	Examiner Benjamin Packard	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/14/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application has been assigned to a new Examiner, who upon review of the case, vacates all previous rejections and restrictions/species elections.

The new examiner intends to restart prosecution de novo. As the first step in that process, the following new restriction requirement is applied to the claims filed 07/14/2008.

Note, because the first elected compound 1(J) was found to be free of the prior art in the Office Action dated 4/12/2007, compound 1(J) will automatically included with any restriction and species election below, as will the currently amended claim 20, which specifically claims the compound 1(J).

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-6 and 10-12, drawn to a method of using a bicyclo compound of Formula (I), with two nitrogen atoms and one oxygen in the ring system (where X=CH₂), classified in class 514, subclass 221.
2. Claims 1-6 and 10-12, drawn to a method of using a bicyclo compound of Formula (I), with two nitrogen atoms and one oxygen in the ring system (where X=O), classified in class 514, subclass 221.

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3. Claims 1-6 and 10-12, drawn to a method of using a tricyclo compound of Formula (I), with two nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 220.
4. Claims 1-6 and 10-12, drawn to a method of using a tricyclo compound of Formula (I), with two nitrogen atoms and one oxygen atom in the ring system, classified in class 514, subclass 119.
5. Claims 1-6 and 10-12, drawn to a method of using a tricyclo compound of Formula (I), with three nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 220.
6. Claims 1-6 and 10-12, drawn to a method of using a tricyclo compound of Formula (I), with three nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 119.
7. Claims 1-6 and 10-12, drawn to a method of using a tricyclo compound of Formula (I), with four nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 220.
8. Claims 1-6 and 10-12, drawn to a method of using a tricyclo compound of Formula (I), with four nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 119.
9. Claims 1-7 and 10-12, drawn to a method of using a polycyclo (greater than tricyclo) compound of Formula (I), with two nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 220.

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10. Claims 1-7 and 10-12, drawn to a method of using a polycyclo compound of Formula (I), with two nitrogen atoms and one oxygen atom in the ring system, classified in class 514, subclass 119.
11. Claims 1-7 and 10-12, drawn to a method of using a polycyclo compound of Formula (I), with three nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 220.
12. Claims 1-7 and 10-12, drawn to a method of using a polycyclo compound of Formula (I), with three nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 119.
13. Claims 1-7 and 10-12, drawn to a method of using a polycyclo compound of Formula (I), with four nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 220.
14. Claims 1-12, drawn to a method of using a polycyclo compound of Formula (I), with four nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 119.
15. Claims 1-7 and 10-12, drawn to a method of using a polycyclo compound of Formula (I), with five nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 220.
16. Claims 1-7 and 9-12, drawn to a method of using a polycyclo compound of Formula (I), with five nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 119.

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17. Claims 13-17, and 22-24, drawn to a bicyclo compound of Formula (I), with two nitrogen atoms in the ring system (where $X=CH_2$), classified in class 514, subclass 221.
18. Claims 13-17, 22-25, and 29 drawn to a bicyclo compound of Formula (I), with two nitrogen atoms and one oxygen in the ring system, where $X=O$, classified in class 514, subclass 211.05.
19. Claims 13-17, 22-24, and 26 drawn to a tricyclo compound of Formula (I), with two nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 220.
20. Claims 13-17, 22-26, and 29 drawn to a tricyclo compound of Formula (I), with two nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 211.04.
21. Claims 13-17, 22-24, and 26 drawn to a tricyclo compound of Formula (I), with three nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 220.
22. Claims 13-17, 22-26, and 29 drawn to a tricyclo compound of Formula (I), with three nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 211.04.
23. Claims 13-17, 22-24, and 26 drawn to a tricyclo compound of Formula (I), with four nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 220.

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24. Claims 13-17, 22-26, and 29 drawn to a tricyclo compound of Formula (I), with four nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 211.04.
25. Claims 13-17, 22-24, 26, and 36 drawn to a polycyclo (greater than tricyclo) compound of Formula (I), with two nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 219.
26. Claims 13-17, 22-26, 29, and 36-37 drawn to a polycyclo compound of Formula (I), with two nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 211.04.
27. Claims 13-18, 22-24, 26, 33-34, and 36 drawn to a polycyclo compound of Formula (I), with three nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 219.
28. Claims 13-18, 22-29, and 33-37 drawn to a polycyclo compound of Formula (I), with three nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 211.04.
29. Claims 13-19, 22-24, 26, 33-34, and 36 drawn to a polycyclo compound of Formula (I), with four nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 219.
30. Claims 13-30, and 33-37 drawn to a polycyclo compound of Formula (I), with four nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 211.04.

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31. Claims 13-19, 22-24, 26, and 33-34 drawn to a polycyclo compound of Formula (I), with five nitrogen atoms in the ring system, where $X=CH_2$, classified in class 514, subclass 219.
32. Claims 13-19, 21-27, and 29-35 drawn to a polycyclo compound of Formula (I), with five nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass 211.04.
33. Claims 13-17, and 30 drawn to a polycyclo compound of Formula (I), with six nitrogen atoms and one oxygen atom in the ring system, where $X=O$, classified in class 514, subclass .

Note, due to the numerous subspecies with Markush groupings of substituted ring constituents claimed in some of the claims, those claims are included in part only as far as the claims read on the specific core species (ie number of rings and number of heteroatoms).

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-12 and 13-37 are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case any one of the structurally distinct compounds of claims 16-37 are asserted to treat the disease of claims 1-16.

Inventions 1-12 are directed to related methods, and Inventions 13-37 are directed to related compounds. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are directed to either a method of using a compound, or the compounds themselves, respectively, where the compounds vary in the number of ring groups and the number of heteroatoms present in the ring structures, resulting in distinct core structures, where the ring systems are considered the core. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

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- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Species Election

This application contains claims directed to the following patentably distinct species:

The various specifically disclosed species of the generic genus of Formula (I), such as the species claimed in claims 9 and 21.

Please elect a single disclosed specie of general formula (I). As noted above, the compound 1(J) will automatically be included in addition to the the above species election.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-19 and 21-37 are generic to the above genus.

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There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

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showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder Notice

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612